

CLAIMS

1. A drug for enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer, which comprises a lactoferrin hydrolysate that can be obtained by hydrolyzing lactoferrin with a hydrolytic enzyme and has an action of enhancing cytotoxic activity of the antibody drug in an antibody therapy of cancer as an active ingredient.
2. The drug according to claim 1, wherein the hydrolytic enzyme is pepsin.
3. The drug according to claim 1 or 2, wherein degradation rate of the lactoferrin hydrolysate is 6 to 20%.
4. The drug according to any one of claims 1 to 3, wherein the lactoferrin hydrolysate has a number average molecular weight of 500 to 5000.
5. The drug according to any one of claims 1 to 4, wherein the cancer is any one of breast cancer, B-cell lymphoma or colon cancer.
6. The drug according to any one of claims 1 to 5, wherein the cancer is a cancer having resistance to the antibody drug.
7. The drug according to any one of claims 1 to 6, wherein the action of enhancing cytotoxic activity of the antibody drug is an action of increasing sensibility of target cells to the antibody drug.
8. A drug for enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer, which comprises any one type or a mixture of two or more types of the following peptides of (a) to (d) as an active ingredient:
 - (a) a peptide having the amino acid sequence of SEQ ID NO: 2;
 - (b) a peptide having the amino acid sequence of the

amino acid numbers 36 to 60 in the amino acid sequence of SEQ ID NO: 1, which includes substitution, deletion, addition or inversion of one or more amino acid residues, and having an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer;

(c) a peptide having the amino acid sequence of SEQ ID NO: 3;

(d) a peptide having the amino acid sequence of the amino acid numbers 36 to 61 in the amino acid sequence of SEQ ID NO: 1, which includes substitution, deletion, addition or inversion of one or more amino acid residues, and having an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer.

9. The drug according to claim 8, wherein the cancer is any one of breast cancer, B-cell lymphoma or colon cancer.

10. The drug according to claim 8 or 9, wherein the cancer is a cancer having resistance to the antibody drug.

11. The drug according to any one of claims 8 to 10, wherein the action of enhancing cytotoxic activity of the antibody drug is an action of increasing sensibility of target cells to the antibody drug.

12. Food or drink comprising the drug according to any one of claims 1 to 11.

13. Food or drink comprising a lactoferrin hydrolysate that can be obtained by hydrolyzing lactoferrin with a hydrolytic enzyme and has an action of enhancing cytotoxic activity of an antibody drug used for an antibody therapy of cancer and attached with an indication that the food or drink is used for enhancing cytotoxic activity of an antibody drug used for an antibody therapy of cancer.

14. A drug for an antibody therapy of cancer, which comprises a lactoferrin hydrolysate that can be obtained by

hydrolyzing lactoferrin with a hydrolytic enzyme and an antibody drug as active ingredients.

15. The drug according to claim 14, wherein the hydrolytic enzyme is pepsin.

16. The drug according to claim 14 or 15, wherein degradation rate of the lactoferrin hydrolysate is 6 to 20%.

17. The drug according to any one of claims 14 to 16, wherein the lactoferrin hydrolysate has a number average molecular weight of 500 to 5000.

18. The drug according to any one of claims 14 to 17, wherein the antibody drug is an anti-CD20 antibody, anti-HER2 monoclonal antibody or anti-17-1A (human tumor-related epithelial cell adhesion factor) antibody.

19. The drug according to any one of claims 14 to 18, wherein the cancer is a cancer having resistance to the antibody drug.

20. A drug for an antibody therapy of cancer, which comprises any one type or a mixture of two or more types of the following peptides of (a) to (d) and an antibody drug as active ingredients:

(a) a peptide having the amino acid sequence of SEQ ID NO: 2;

(b) a peptide having the amino acid sequence of the amino acid numbers 36 to 60 in the amino acid sequence of SEQ ID NO: 1, which includes substitution, deletion, addition or inversion of one or more amino acid residues, and having an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer;

(c) a peptide having the amino acid sequence of SEQ ID NO: 3;

(d) a peptide having the amino acid sequence of the amino acid numbers 36 to 61 in the amino acid sequence of SEQ ID NO: 1, which includes substitution, deletion,

addition or inversion of one or more amino acid residues, and having an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer.

21. The drug according to claim 20, wherein the antibody drug is an anti-CD20 antibody, anti-HER2 monoclonal antibody or anti-17-1A (human tumor-related epithelial cell adhesion factor) antibody.

22. The drug according to claim 20 or 21, wherein the cancer is a cancer having resistance to the antibody drug.

23. Use of a lactoferrin hydrolysate that can be obtained by hydrolyzing lactoferrin with a hydrolytic enzyme and has an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer for the production of a drug for enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer.

24. Use of any one type or a mixture of two or more types of the following peptides of (a) to (d) for the production of a drug for enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer:

(a) a peptide having the amino acid sequence of SEQ ID NO: 2;

(b) a peptide having the amino acid sequence of the amino acid numbers 36 to 60 in the amino acid sequence of SEQ ID NO: 1, which includes substitution, deletion, addition or inversion of one or more amino acid residues, and having an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer;

(c) a peptide having the amino acid sequence of SEQ ID NO: 3;

(d) a peptide having the amino acid sequence of the amino acid numbers 36 to 61 in the amino acid sequence of SEQ ID NO: 1, which includes substitution, deletion, addition or inversion of one or more amino acid residues,

and having an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer.

25. A method for enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer using the antibody drug, wherein a lactoferrin hydrolysate that can be obtained by hydrolyzing lactoferrin with a hydrolytic enzyme and has an action of enhancing cytotoxic activity of the antibody drug in an antibody therapy of cancer is administered to a patient.

26. A method for enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer using the antibody drug, wherein any one type or a mixture of two or more types of the following peptides of (a) to (d) is administered to a patient:

(a) a peptide having the amino acid sequence of SEQ ID NO: 2;

(b) a peptide having the amino acid sequence of the amino acid numbers 36 to 60 in the amino acid sequence of SEQ ID NO: 1, which includes substitution, deletion, addition or inversion of one or more amino acid residues, and having an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer;

(c) a peptide having the amino acid sequence of SEQ ID NO: 3;

(d) a peptide having the amino acid sequence of the amino acid numbers 36 to 61 in the amino acid sequence of SEQ ID NO: 1, which includes substitution, deletion, addition or inversion of one or more amino acid residues, and having an action of enhancing cytotoxic activity of an antibody drug in an antibody therapy of cancer.